

REMARKS

In this response to the Office Action dated December 9, 2009, Applicants have canceled Claims 18-20 and 23-25 without prejudice. Claims 21, 32, and 33 have been amended. New claims 34-37 have been added. As discussed below, no new matter is added in these amendments. Upon entry of the amendments, claims 21 and 26-37 are pending.

In light of the amendments and remarks as set forth herein, Applicants respectfully request withdrawal of the claim rejections and consideration of pending claims for the patentability.

Discussion of Claim Amendments

Claims 21 and 32 have been amended to incorporate the features of claim 25, which is now canceled. Further support to these amendments can be found, for example, from Table 1, Example 1, and Figures 2 and 4 of the specification as originally filed.

Support for the amendment to claim 22 as well as for new claim 34 can be found, for example, from Example 1 of the specification.

Support for the new claims 35-37 can be found, for example, from page 2, lines 11-12 of the specification.

As such, the claim amendments in this response are fully supported and do not constitute any new matter. Applicants respectfully request entry of the amendments.

Claim rejections under 25 U.S.C. 112, second paragraph

Claims 18-21 and 23-33 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite.

Claim 18 and its dependent claims as well as claim 21 and its dependent claims were rejected due to use of an acronym "GBM" at its first occurrence without a full definition. Claim 21 has been amended and the full definition of "GBM" is now cited in claim 21 as set forth above. Therefore, claims 21 and its dependent claims are now in compliance with 35 U.S.C. 112, second paragraph. Applicants respectfully request reconsideration of claim 21 and its dependent claims. As claim 18 and its dependent claims 19 and 20 have been canceled, the rejection to these claims is now moot.

Regarding claim 32, the Examiner asserted that it is unclear if affinity "of the antibody" is with respect to a kidney tissue sample or to some other undefined nephritis sample and thus rejected the claim. Claim 32 has been amended and more explicitly explain that the antibody is configured to have a substantially higher affinity to a frozen kidney tissue obtained from a mammal under condition of nephritis than a frozen kidney tissue obtained from a mammal under a normal condition. In light of this amendment, Applicants respectfully request reconsideration of claim 32.

Claim 33 was rejected for lacking antecedent basis. Claim 33 has been amended such that the lack of antecedent basis is no longer present in the claim. Applicants respectfully request reconsideration of claim 33.

Claim rejections under 103(a)

Claims 21, 23, 24, and 26-31 were rejected under 35 U.S.C. 103(a) as being unpatentable over Yokoyama (Cell 35: 40, 2003), further in view of Campbell, Cosmo Bio Co. Ltd., Sugihara *et al.* (J. Pathol. 178: 352, 1996), and Johansson *et al.* (J. Biol. Chem. 267: 24533, 1992).

Claim 21 has been amended to incorporate the features of Claim 25, which was not rejected as obvious over the cited references. Accordingly, Claim 21 now recites, among others, that a method of identifying presence of nephritis in a mammal at an early stage before formation of glomerular crescent, comprising: obtaining a biological sample of frozen kidney tissue from the mammal; exposing the sample to anti-noncollagenous domain of type IV collagen (NC1) monoclonal antibody, wherein said antibody exhibits substantially more binding to glomeruli of macaques in which nephritis has been induced by anti-glomerular basement membrane (GBM) antibody than to glomeruli of normal macaques; and identifying binding of the antibody to antigen present in the sample, wherein significant binding indicates presence of nephritis in the mammal.

Applicants respectfully submit that all the cited references fail to teach or suggest every feature of claim 21 as presently amended. For example, Yokoyama does not teach the method of identifying presence of nephritis in a sample that is a frozen kidney tissue obtained from a mammal. Further, Campbell, Cosmo Bio Co. Ltd., Sugihara, and Johansson are also silent in teaching or suggesting a method of identifying nephritis with a frozen kidney sample. As such, even if all of the cited references were combined, such combination would still fail to teach or

suggest the method according to claim 21. Therefore, claim 21 is not and cannot be obvious over the prior art. Accordingly, reconsideration of claim 21 is respectfully requested. As to claims 26-31, they incorporate all the features of claim 21 through their dependencies from claim 21. As such, these dependent claims 26-31 should also be patentable for at least the same reasons that claim 21 is patentable as well as for their additional patentable features. Accordingly, reconsideration of claims 26-31 is also requested. As claims 23 and 24 have been canceled in this response, the rejection to these claims is now moot.

Claims 18-20 were rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Yokoyama, together with Cosmo Bio Co. Ltd., Otfshun *et al.* (US 5871649), Sugihara, and applicant's specification at page 12 for reasons similar to those of record in the prior rejection of the similar subject matter of these claims. While Applicants disagree with the Examiner, to expedite the prosecution, Applicants have canceled claims 18-20. As such, the rejection to claims 18-20 is now moot.

Allowability of New Claims 35-37

New claims 35-37, through their dependencies, incorporate all the features of claim 21, 32, and 33, respectively and further define the subject matter. As noted, claims 21, 32, and 33 are in condition of allowance. Therefore, new claims 35-37 would also be in condition of allowance for at least the same reasons that its respective base claim is allowable and for its own patentable features. Accordingly, favorable consideration and allowance of new claims 35-37 is respectfully requested.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution.

Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

In view of Applicants' foregoing Amendments and Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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